REMARKS

Claims 1-7, 9-11 and 21-22 have been amended grammatically.

Claims 1-7 have been amended to recite that the reactant alcohol is serine. Support for this amendment can be found in original claim 1 in Examples 2-5.

Claims 1-7 have been amended to recite the phosphatide compositions of the invention are sodium salts. Support for this amendment can be found in Examples 2-5.

The limitation that the reaction of the present invention occurs in a single aqueous phase has been deleted from claims 1-7.

The limitation that the phospholipase D of the present invention is purified by eluting on an anionic cationic exchange resin at a pH of 6.2 has been moved from claims 1 and 2 to claims 3 and 4.

Claims 1 and 3 have been amended to recite that the reactant phosphatides of formula II are obtained from soybean. Support for this amendment can be found in the second paragraph of the Specification and Example 7.

Claims 2 and 4 have been amended to recite that the reactant phosphatides of formula II are obtained from egg. Support for this amendment can be found in the second paragraph of the Specification and Example 3.

Claim 8 has been amended to delete limitations other than the limitation reciting the *Streptomyces hachijoense* strain is ATCC 19769.

The "made by the process" language of claims 10 and 11 has been deleted.

New dependent claims 20 and 21 have been added. They depend from claims 1 and 2 respectively, but claim 20 recites the limitation that the phosphatidyl-L-serine composition is at least 95% pure. Claim 21 recites that the phosphatidylcholine reactant is completely converted to product in the reaction. Support for these amendments can be found in the table bridging pages 4-5 of the specification, and Examples 3 and 7.

The claims have been amended to more clearly describe the present invention.

No new matter has been added.

1. Claim Rejections under 35 USC §112, Second Paragraph

The Examiner has rejected claims 1-11 and 15-19 as allegedly indefinite. In particular, the Examiner requires clarification regarding the claim language reciting "a phosphatidyl-L-serine product having a fatty acid composition identical to that of ... lecithin." The Examiner states PDR Health discloses that "lecithin" refers to phosphatidylcholine and not phosphatidylserine as claimed, allegedly making the claim confusing (Office Action, page 2). Applicants respectfully traverse.

Applicants point out that the fatty acid portion of a lecithin/phosphatidylcholine reactant is covalently linked to a serine reactant by phospholipase D to yield the phosphatidylserine of the present invention. It follows that the fatty acid portion of the phosphatidylserine of the present invention has identical to the fatty acid composition as the lecithin/phosphatidylcholine reactant. Applicants therefore submit that the claim language is indeed clear, and respectfully request withdrawal of the rejection.

The Examiner also states the product of the reaction recited in claims 1-11 and 15-19 does not appear to be a phosphatidyl-L-serine product, which makes the claims indefinite and confusing (Office Action, page 2). Applicants respectfully traverse.

Applicants have amended the claims to recite that the alcohol reactant of the invention is serine, thereby obviating the rejection.

The Examiner has rejected claim 8 on the grounds that the recited formula I phosphatide reactant allegedly lacks antecedent basis for being phosphatidyl-L-serine (Office Action, page 3). Applicants respectfully traverse.

Applicants have amended claim 7 to recite the composition of the present invention is a phosphatidylserine sodium salt, and to recite the alcohol reactant is serine. Applicants have also amended claim 8 to only recite the further limitation that the *Streptomyces hachijoense* strain used to catalyze the reaction is ATCC 19769; thereby obviating the rejection.

The Examiner has rejected claims 10 and 11 as allegedly indefinite because claims 3 and 4 are not process claims (Office Action, page 3). Applicants respectfully traverse.

Applicants have deleted the "made by the process" language of claims 10 and 11, thereby obviating the rejection.

The Examiner has objected to claim 8 for allegedly improper form (Office Action, page 3). Applicants respectfully traverse.

Applicants have amended claim 8 as discussed above, thereby obviating the rejection.

2. Claim Rejections under 35 §102(b)

2.1 Puricelli et al. (EP0329053)

The Examiner has rejected claims 5, 7 and 8 as allegedly anticipated by Puricelli et al. In particular, the Examiner states that Puricelli et al. disclose phosphatides having the same structure as those of the present invention, which are recognized as a useful pharmaceuticals and food additives (Office Action, page 6). Applicants respectfully traverse.

Applicants have amended the claims to recite a phosphatidylserine sodium salt composition. In contrast, Puricelli teaches esters and diesters of glycerophosphoric acids that have a different structure than the phosphatidylserine sodium salt of the present invention:

The molecules according to Puricelli formula I (page 3 and claims) are comprised of at least two phosphate groups linked by phosphodiester bonds. In contrast, Applicants claimed phosphatides comprise only a single phosphate group.

The molecules according to Puricelli formula I (page 3 and claims) lack a diacylglycerol group in the R position of the phosphatidylserine of the present invention (*i.e.* the molecule lacks an acetyl group).

The molecule according to Puricelli formula III (page 4) lacks the diacylglyceride group in the R position of the phosphatidylserine of the present invention.

The molecule according to Puricelli formula IV (page 4) lacks any phosphate group at all, in contrast to the phosphatidylserine of the present invention.

The molecule according to Puricelli formula V (page 4) also lacks a diacyglycerol group in the R position of the phosphatidylserine of the present invention.

In light of the foregoing, Puricelli et al. fail to teach molecules that anticipate the phosphatidylserine sodium salt of present invention. Applicants respectfully request reconsideration and withdrawal of this rejection.

2.2 Chemical Land

The Examiner has rejected claims 6-8 as allegedly anticipated by Chemical Land 21. The Examiner contends Chemical Land 21 discloses a diacetyl phosphatide that has the same structure as the phosphatides of the present invention (Office Action, pages 4-5). Applicants respectfully traverse.

Applicants point out that the chemical formula of the molecule taught by Chemical Land 21 is: $C_3H_5OH(CH_3COO)_2$. Because this molecule does not contain any phosphate groups, as do the molecules of the present invention, it fails to anticipate. Applicants therefore respectfully request reconsideration and withdrawal of the rejection.

2.3 Horribin et al. (U.S. Patent No. 5,446,841)

The Examiner has rejected claims 6-8 as allegedly anticipated by Horribin et al. The Examiner alleges Horribin discloses a phosphatide that has the same structure as the phosphatides of the present invention, and is suitable for use as a cosmetic agent or food additive (Office Action, page 6). Applicants respectfully traverse.

Horribin teaches chemically-synthesized pure phospholipids composed of two essential fatty acids (*i.e.* phospholipids consisting of a single type of fatty acid attached to each position of the diacylglycerol group). These fatty acids can be oleic acid, parinaric acid, columbinic acid and fatty acids selected from the twelve n-6 and n-3 essential fatty acids, but not palmitic acid (Horribin et al. Table 1; Column 2, lines 65-67; and Column 3, line 52).

In contrast, the phosphatidylserine composition of the present invention is obtained from a phospholipase D catalyzed transphosphatidylation reaction in which soybean or egg lecithin and serine are the starting reagents. Consequently, the fatty acid groups of Applicants' phosphatidylserine composition is identical to the fatty acid composition of soybean or egg lecithin.

It is well known that lecithin obtained from soybean or egg is actually comprised of a population of molecules with respect to the fatty acid groups of the lecithin molecules. For example,

soybean lecithin is comprised of a population of molecules, about 40% of which have linoleic acid at the 1-position and about 35% of which have palmitic acid at the 1-position. In addition, about 76% of soybean lecithin molecules have linoleic acid at the 2-position. As discussed above, the phosphatidylserine composition of the present invention is made up of a population of phosphatidylserine molecules having the same fatty acid group distribution as soybean (or egg) lecithin (an appreciable portion of which is palmitic acid); whereas Horribin teaches a pure population of phosphatidylserine molecules having one fatty acid makeup (which does not include palmitic acid).

It follows that, because Horribin teaches phosphatide compositions different than those of the present invention, Horribin is not an anticipating reference. Applicants request reconsideration and withdrawal of the rejection.

2.4 De Ferra et al. (U.S. Pat. No. 5,700,668)

The Examiner has rejected claims 6-8 as allegedly anticipated by or, in the alternative, obvious over De Ferra et al. The Examiner states De Ferra teaches enzymatically produced phosphatidylserine compositions having fatty acid compositions identical to that of soybean and egg lecithin and presumed to have a peroxidation of less than 5 (Office Action, page 7). The Examiner concludes that De Ferra anticipates the present invention. Applicants respectfully traverse.

As discussed above, the claims have been amended to recite the phosphatidylserine of the present invention is a sodium salt. In contrast, De Ferra teaches a phosphatidylserine produced exclusively as a calcium salt (De Ferra et al. Examples 2-5). It is well known that phosphatidylserine sodium salt has preferable solubility, and therefore preferable gastric dissolution and intestinal absorption characteristics than phosphatidylserine calcium salt. It follows that the phosphatidylserine sodium salt of the present invention is both novel and nonobvious over the phosphatidylserine calcium salt taught by De Ferra et al. Applicants therefore request reconsideration and withdrawal of this rejection.

3. Claim Rejections under §103

The Examiner has rejected claims 1-11 and 15-19 as allegedly obvious over De Ferra et al. in view of Horribin, Puricelli, Chemical Land and Kurihara (U.S. Patent No. 5,785,984). The Examiner's reasoning for this rejection may be found on pages 8-10 of the Office Action, and is not reproduced here. Applicants respectfully traverse.

As discussed above, the De Ferra, Horribin, Puricelli and Chemical Land references all fail to teach the phosphatidylserine sodium salts of the present invention, even when combined. The further inclusion of the teachings by Kurihara et al. fails to cure the deficiency. In particular, the Kurihara reference fails to disclose phosphatidyl serine at all. It follows that, even when combined, the Horribin, Puricelli, Chemical Land and Kurihara references fail to teach the phosphatidylserine sodium salt of the present invention. It is therefore submitted that the obviousness rejection is improper, and Applicants respectfully request reconsideration and withdrawal of this rejection.

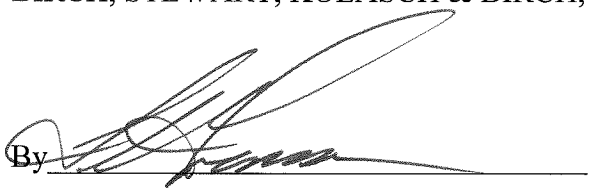
Pursuant to 37 C.F.R. §§ 1.17 and 1.136(a), the Applicant respectfully petitions for a two (2) month extension of time for filing a response in connection with the present application and the required fee of $450.00 is to be charged to Deposit Account No. 02-2448.

Should there be any outstanding matters that need to be resolved in the present application; the Examiner is respectfully requested to contact Leonard R. Svensson (Reg. No. 30,330) at the telephone number of the undersigned below, to conduct an interview in an effort to expedite prosecution in connection with the present application.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37 C.F.R. § 1.16 or under 37 C.F.R. § 1.17; particularly, extension of time fees.

Respectfully submitted,

BIRCH, STEWART, KOLASCH & BIRCH, LLP



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